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Science Based Approaches and the Precautionary Principle

EU Perspectives from crop protection

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ABA Section of Environment, Energy and Resources & CropLife America Annual Event,

New Developments in Pesticide Law and Policy

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"exceptional expertise on EU regulations on chemical…and a great ability to understand the complexity of businesses."
Chambers & Partners Europe, 2019

- **English barrister, *Avocat* at the Brussels Bar**, partner resident in Brussels.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market.**
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.

Topics

- **Precautionary Principle:**
  - legislation (Treaties and PPP regime)
  - policy
  - courts
  - focus on Bees

- **New Transparency Regime – a response to over precaution?**

28 Years of (official) Precaution

Appears only once in the TFEU, and is not defined (Art 191):

'2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.
(…)
3. In preparing its policy on the environment, the Union shall take account of:
- available scientific and technical data (…)
- the potential benefits and costs of action or lack of action'

Court Application (implicit and explicit)

CJEU was using precaution in areas beyond "environmental" *before* confirming a wider scope:

Early days: The PP and free movement of goods

- CJEU reviewed whether Member State measures that impede intra-EU trade may nevertheless be justified on grounds of public health protection, where scientific uncertainty prevails: *"The fact that the* [pesticide] *quantities absorbed by the consumer, in particular in the form of residues on foodstuffs, can neither be predicted nor controlled justifies strict measures intended to reduce the risks faced by the consumer*" *(*Case 94/83 – *Heijn*, paragraph 15)

BSE Cases (C-180/96 & C-157/96): Temporarily banning export of bovine animals, meat and derived products from UK to other MSs.

- Decision taken when 'great uncertainty' on risks.
- EU institutions may act to protect 'human health'.
- "Emergency"& Temporary measure to be 'subjected to detailed scientific study and … review …'.

The General Court has stated on multiple occasions that the precautionary principle is a general principle of EU law.

Court Application (implicit and explicit)

Being a general principle ≠ "no limits".

- **C-6/99, Greenpeace France case**: ECJ rejected the argument that PP could be applied as a free-standing "trump card" where PP already forms part of the regulatory regime for placing a product on the market in the EU.
  - Where EU harmonised risk assessment procedure: neither Commission nor MSs can apply PP in conflict with underlying secondary legislation (e.g. safeguard clauses or other provisions dedicated to the handling of new information).
  - Where no harmonisation: autonomous application (to justify restrictive measures) subject to overarching EU law obligations (e.g. free movement of goods).

Commission Policy on Precaution

2 February 2000, PP Communication sets out Commission's policy on precaution:

Application PP presupposes

1. Identification of potentially dangerous effects
2. Scientific evaluation does not allow the risk to be determined with sufficient certainty

How to decide if to apply PP:

- 'Should start with a scientific evaluation, as complete as possible', identifying level of uncertainty at each stage.
- Decision whether or not to act
- Transparent decision-making procedure.
- Involve 'all interested parties …as early as possible and to the extent reasonably possible.'

Commission Policy on Precaution

When applied (as part of risk management):

- Range of actions may be taken (not always legally binding)
- Measures must be
  - proportional to the level of protection (which cannot be zero risk);
  - non-discriminatory;
  - consistent with similar measures already taken;
  - based on examination of potential benefits and costs of action or lack of action; and
  - subject to review.

Subsequent Court Approach to Precaution

Two complementary components of risk assessment which 'must not be confused':

1. Conducting a scientific assessment of the risks

- Does not have to be conclusive BUT ...
- Must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society and which measures appear to it to be appropriate and necessary to prevent the risk from materializing

Subsequent Court Approach to Precaution

Two complementary components of risk assessment which 'must not be confused':

2. Ascertaining what level of risk is deemed unacceptable

- political choice turning on the facts of each case, taking into account factors including:
- severity of the impact on human health were the risk to occur;
- extent of possible adverse effects;
- persistency or reversibility of those effects;
- possibility of delayed effects; and
- even the more or less concrete perception of the risk based on available scientific knowledge.

Subsequent Court Approach to Precaution

Role of Scientific Expert Committees:

- Although consulted under various pieces of legislation by the Commission, the opinions they deliver are NOT binding.
- EU institution that disregards (wholly/partly) an opinion, 'must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding' it.
- The statement of reasons must be of a scientific level at least commensurate with that of the opinion

PPP Regulation itself and Precaution

No mention in Dir. 91/414, but Reg. 1107/2009:

- Subject Matter & Purpose, Art. 1(4) :

  "The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

- Approval Regulations, Art. 13(2):

  "On the basis of the review report, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, a Regulation shall be adopted…"

PPP Regulation confirmed consistent with PP

C-616/17 Blaise (2 October 2019): Even PPP Regulation has been challenged: whether compatible with PP?

- EU legislature has an obligation to comply with the precautionary principle when adopting rules (including identification of the potentially negative consequences for health, comprehensive assessment of the risk "based on the most reliable scientific data available and the most recent results of international research") – otherwise "manifest error of assessment". Court concluded :"has revealed nothing capable of affecting the validity of Regulation (EC) No 1107/2009."
  - Criteria set out for the identification of an active substance by the applicant, and obligations on it to identify the active substance does not mean it can choose at discretion the scope of the active substance.
  - Cumulative effects of substances in a product are sufficiently considered.
  - Provisions on validity of the tests, methods of analysis, evaluation by Member States etc. avoided bias because the applicant is the submitter
  - Rules related to the public access to information (as interpreted by the Court in particular in Case C-442/14 Bayer CropScience and Stichting De Bijenstichting but also in Case T-545/11 RENV Stichting Greenpeace Nederland and PAN Europe v. Commission) are suitable.
  - Rules do not exempt submission of studies of carcinogenicity and toxicity for authorization.

The Bees cases

Court Approaches to Precaution

May 2018, General Court issued judgments in 3 cases on alleged effects of certain active substances on bee colony survival and development (point 3.8.3 of Annex II to Regulation 1107/2009):

- Case T-584/13, BASF Agro BV v Commission
- Case T-429/13, *Bayer CropScience AG v Commission* (Appeal pending: Case C-499/18 P)
- Case T-451/13, *Syngenta Crop Protection AG v Commission*

Important because:

- breach of the precautionary principle was the basis for partial annulment in BASF
- explain role of the PP in Reg. 1107/2009 and decisions based upon it
- examine extent of Commission's powers to review active substance approvals

Court Approaches to Precaution

On the precautionary principle

- Confirmation that 2000 Communication **requires an "*examination of the benefits and costs of action and lack of action*" – which *includes* but is more than cost-benefit economic analysis (socio-economics , efficacy etc.).**
- **The "purely economic element of the impact assessment…is required in all circumstances"**
- The obligation to carry out an impact assessment "is ultimately no more than **a specific expression of the principle of proportionality**"
- An indispensable **corollary of a wide discretion**: "*if the individual must accept that he may be barred from carrying on an economic activity even though it is not even certain that it entails an unacceptable risk, the administration must at least be required to assess fully, as far as possible, the consequences of its action, as against the possible consequences of its inaction, for the various interests at stake.*"

Court Approaches to Precaution

Enough for BASF case because the Commission : "*...did not submit any evidence to show that such an analysis was in fact carried out. On being questioned in that respect at the hearing, the Commission acknowledged that there was no documentary proof....the College of Commissioners, was aware of the analysis that had been conducted for the purposes of the earlier decision*".

However – a reductionist reading:

- "the requirements of the Communication on the precautionary principle are satisfied where the authority concerned — in the present case, the Commission — has in fact acquainted itself with the effects, positive and negative, economic and otherwise, to which the proposed action, as well as the failure to act, may lead, and has taken that into account in its decision. By contrast, it is not necessary for those effects to be estimated precisely, if that is not possible or would require disproportionate effort."
- "format and scope of that examination are not specified".
- Not necessarily "a specific assessment procedure culminating, for example, in a formal, written assessment report".
- "considerable discretion regarding methods of analysis".
- Reiterates Communications' assertion that "in certain circumstances, economic considerations must be considered less important than other interests which are given priority; interests such as the environment or health are expressly mentioned by way of example".
- "not necessary for the economic analysis… to be made on the basis of a precise calculation of the respective costs… will in most cases be impossible to make"

New Data Transparency Regime

27 March 2021

Targets: EU sectoral legislation in eight areas

1. the deliberate release into the environment of genetically modified organisms (GMOs),
2. GM food and feed,
3. feed additives,
4. smoke flavourings,
5. food contact materials,
6. food additives, food enzymes and food flavourings,
7. plant protection products (agrochemicals),
8. novel foods

Notification of studies

New EFSA **Database of studies** "*commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion*".

System of double entry cross-verification:

- **business operators** shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.
- also **laboratories and other testing facilities located in the Union** shall also, without delay, notify the same infor to EFSA, as well as the name of the business operator who commissioned such a study.

Extra-territorial application for labs and other testing facilities "located in third countries insofar as set out in relevant agreements and arrangements with those third countries…"

Very Wide Range of Materials To Be Made Public

Includes the following to be "made public without delay":

- scientific data, studies and other information supporting applications, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion * * *
- the information on which EFSA's scientific outputs, including scientific opinions are based*
- EFSA's scientific studies in accordance with Articles 32 (commissioned under old regime) and 32d (new regime verification studies);
- a summary of the advice provided to potential applicants at pre-submission phase pursuant to Articles 32a (pre-submission advice) and 32c (consultation with 3rd parties) * *

If *, only made public once an application has been considered valid or admissible.

If ***, assertion that ≠ granting IP rights or data exclusivity rights**

If *, assertion that no explicit or implicit license to use and signed undertakings will be given be accessors to this effect

If red text, will be on EFSA website, for downloading, printing and in electronic searchable formats

CBI Claims: new burden of proof (reversal) & highest threshold

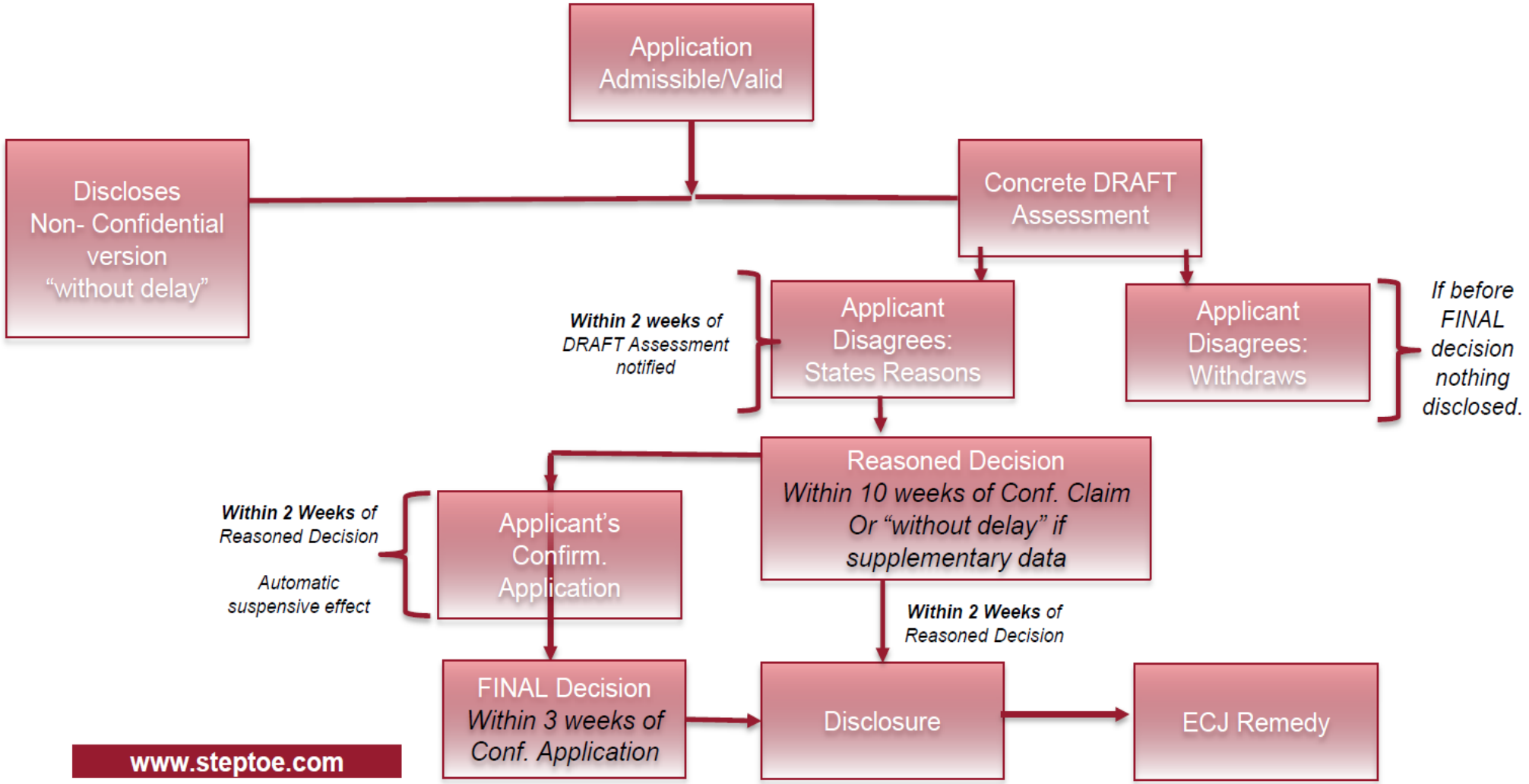
Confidential treatment my be claimed by an Applicant based on an exhaustive list of information where the disclosure of such information is demonstrated by the applicant "to potentially harm its interests to a significant degree" (claim to be accompanied by "verifiable justification"):

- the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion;
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- commercial information revealing sourcing, market shares or business strategy of the applicant; and
- quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion.

PLUS sector specific additions (by amendment to those schemes) which EFSA "may also" treat as confidential based upon the same threshold test:

- *PPPR adds what was previously deemed to be CBI*

Timing of disclosure (faster than anywhere else)



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Take Home Messages

Take home messages

- The precautionary principle underpins the EU PPP Regulation – and permeates its application.
- Its lawful application presupposes identification of effects and scientific uncertainty – cannot just be applied at will. This includes: a scientific evaluation and cost benefit analysis.
- It is important to understand the lawful limits on the application of the principle – as part of your dossier advocacy. These limits are shaped, to a large extent, by the case law of the CJEU in this area.
- One response to perceived lack of faith in public authority decision making is:
  - a tendency to be overly cautious
  - AND very soon far greater transparency for PPPs than ever before (and litigation?).